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Title: **INHALER**

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INHALER

The present invention relates to an inhaler for delivery of medicament by inhalation, particularly but not exclusively to a breath-actuated inhaler.

5 Inhalers are commonly used for delivery of a wide range of medicaments. The inhaler holds a cannister of medicament which is actuated by compression to deliver a dose of medicament through a mouthpiece. The inhaler may be provided with an actuation mechanism for compressing the canister. This may be a breath-actuated mechanism which is arranged to actuate the canister in response to
10 inhalation at the mouthpiece. Typically, a breath-actuated inhaler includes a pre-loading mechanism for loading a resilient loading element with an actuation force for compression of the canister and a triggering mechanism arranged to hold the resilient loading element against compression of the canister and to release the resilient loading element on inhalation.

15 Known canisters comprise a body having a protruding valve stem and an internal metering chamber which receives a dose of medicament stored in the body. Compression of the valve stem into the body causes the medicament in the metering chamber to be delivered out of the valve stem as a dose. The valve stem is biased outwardly to re-set the canister after compression to deliver the next dose of
20 medicament. However, if the compression of the canister is released to allow re-set of the valve stem too early, then a full dose is not properly delivered. The present invention is intended to ensure proper delivery of a full dose.

According to the present invention there is provided an inhaler for delivering medicament by inhalation, comprising:

25 a housing for holding a canister of medicament having a body and a valve stem compressible together to actuate the canister to deliver a dose of medicament from the valve stem;

an actuation mechanism for compressing the canister,

a cannister re-set mechanism comprising a locking element for locking the
30 canister in a compressed state and a release member resiliently biased by the actuation mechanism on compression of the canister to release the locking

mechanism to allow reset of the canister.

By provision of the locking element for locking the canister in a compressed state, it is possible to ensure re-set does not occur immediately. The release member subsequently releases the locking mechanism to allow re-set of the canister after a proper dose has been delivered.

Preferably, the cannister reset mechanism further comprises a damping element for damping movement of the release member to delay the action of the resilient biasing to release the locking element a predetermined period of time after actuation of the canister.

10 The damping element may comprise a rotor disposed in a viscous fluid and driven by movement of the release member which is advantageous because it has a minimal size for the desired degree of damping. However other damping elements may be contemplated, such as an expanding foam or a tortuous path.

By use of a damping element to delay release of the compressed canister, it is possible to control the period for which the canister is held compressed. Typically, such a period will be between 100 and 5000 ms. Use of damping has been found to be advantageous over a mechanical arrangement introducing a time delay. A mechanical arrangement must be manufactured with tight tolerances to properly control the delay and tend to decrease in precision over time. In contrast a damping element is easily controllable and does not lose timing accuracy.

Advantageously, the locking element is a knee joint having a locked position for holding the canister in a compressed state and the release member engages the knee joint to break the knee joint into a broken position for releasing the canister. A knee joint is particularly suitable, because it can securely lock the canister in a compressed state and yet be simply relatable.

The present invention may suitably apply to a canister, wherein the actuation mechanism comprises:

a pre-loading mechanism for loading a resilient loading element with an actuation force using a loading member coupled to the resilient loading member and movable from a first position where the resilient loading element is relaxed to a second position where the resilient loading element is loaded, the resilient loading

element being arranged when loaded to bias compression of the canister, and
a triggering mechanism arranged to hold the resilient loading element
against compression of the canister and to release the resilient loading element to
allow compression of the canister.

5 In this case, the locking element may be arranged to lock the loading
element in its second position for locking the canister in its compressed state after
release of the triggering mechanism. Such a structure prevents the locking element
from interfering with the operation of the actuation mechanism to deliver a dose.

Conveniently, the release member is resiliently biased by a coiled spring,
10 the coils of which encircle the loading member.

Desirably, the pre-loading mechanism further comprises a canister
engagement lever biased by the resilient loading element when loaded to compress
the canister, the triggering mechanism engaging the cannister engagement lever to
hold and release the stored actuation force, wherein the release member is resiliently
15 biased by a resilient biasing element acting between the canister engagement
member and the release member. As the canister engagement member itself
compresses the canister, this prevents movement of the release member before
compression of the canister and hence reduces the chance of a premature re-set of the
canister.

20 To allow a better understanding, an inhaler which embodies the present
invention will now be described by way of non-limitative example with reference to
the accompanying drawings, in which:

Fig. 1 is a front view of the inhaler held in a hand;

Fig. 2 is a side view of the inhaler;

25 Fig. 2A is a side view of the inhaler without a closure element fitted;

Fig. 3 is a side view of the inhaler with a lower housing portion being
removed;

Fig. 4 is a side view of an upper housing portion of the inhaler with a
canister being removed;

30 Fig. 5 is a side view of an alternative form of collar for connecting the
closure element to the canister;

Fig. 6 is a cross-sectional view taken along line VI-VI in Fig. 5;

Fig. 7 is a side view of the canister mounting arrangement and actuation mechanism;

Fig. 8 is a view from the rear and side of the actuation mechanism;

5 Fig. 9 is a view from the rear and the opposite side from Fig. 8 of the actuation mechanism;

Fig. 10 is a front view of the arrangement for loading the actuation mechanism;

10 Fig. 11 is a side view of an alternative form of button arrangement for loading the actuation mechanism;

Fig. 12 is a view of certain parts of the actuation mechanism from the front and side;

Figs 13 to 16 are schematic views of the actuation mechanism illustrating respective states over a complete cycle of operation; and

15 Fig. 17 is a view of the electronic timer circuit.

An inhaler 1 which embodies the present invention is illustrated in Figs. 1 and 2, respectively showing the front view of the inhaler 1 held in a user's hand and a side view of the inhaler.

20 The inhaler has a housing 2 comprising an upper housing portion 3 and a lower housing portion 4 which are coupled together. The upper and lower housing portions 3 and 4 have outer walls which are hollow to define a space accommodating a canister 5 of medicament and an actuation mechanism 6 operatable to actuate the canister 5 to deliver a dose of medicament.

25 The upper housing portion 3 has opposed side walls 7 joined by a flat front wall 8, a curved rear wall 9 and a top wall 10. The lower housing portion 3 has opposed side walls 11 fitting flush with the side walls 7 of the upper housing portion 3 and a curved rear wall 12 fitting flush with the rear wall 9 of the upper housing portion 3. The rear walls 12 and 9 together form a curved surface comfortably received in the palm of the user's hand as illustrated in Fig. 1. A mouthpiece 13
30 protrudes from the lower housing portion 4 and may be protected by a cap 14 hinged to the lower housing member 4 to be openable as illustrated in Fig. 2.

The front of the lower housing member 4 between the side walls 11 is open to define a vent in the outer surface of the housing 2 adjacent the mouthpiece 13 between the upper and lower housing portions 3 and 4. The vent 15 is closed by a closure element 16 fitting flush with the front wall 8 of the upper housing portion 3 to form part of the outer wall of the housing 2.

The upper and lower housing members are coupled by a coupling 17 allowing the lower housing member 4 to be slid off as illustrated in Fig. 3.

The canister 5 fits in the upper housing portion 3 and may be slidably removed for replacement as illustrated in Fig. 4.

The canister 5 comprises a generally cylindrical body 18 and a valve stem 19 which are compressible together to deliver a dose of medicament from the valve stem 19. The canister is of a known type including a metering chamber which captures a defined volume of medicament from the body 18 of the canister 5, which volume of medicament is delivered as a metered dose from the valve stem 19 on compression of the valve stem 19 relative to the body 18. The valve stem 19 is weakly biased outwardly to reset the canister 5 after compression for refilling the metering chamber. The valve stem 19 is received in a nozzle block 20 which is arranged to direct a dose of medicament delivered from the valve stem 19 out of the inhaler 1 through the mouthpiece 13.

The closure element 16 is connected to the canister 5 by a collar 21 fitted around a necked portion 22 of the canister body 18. The collar 21 is permanently fixed to the closure element 16 and may be integral therewith. The collar 21 is restrained by the necked portion 22 of the canister 5 such that the closure element 16 is removed and replaced together with the canister 5 as illustrated in Fig. 4. The canister 5 and collar 21 have a small degree of relative movement along the axis of the canister 5. This allows actuation of the canister by compression of the canister body 18 towards the valve stem 19 when the stem 19 is fixed relative to the inhaler 1 in the nozzle block 20 and the collar 21 is also fixed by the closure element 16 fitting as part of the housing 2 of the inhaler 1.

Figs. 5 and 6 respectively illustrate a side view and cross-sectional view and alternative collar 23 for connecting the closure element 16 to the canister 5. The

collar 23 includes a cylindrical portion 24 held on the necked portion 22 of the canister body 18 by a protrusion 25 formed in the cylindrical portion 24 by a U-shaped cut-out 26. The cylindrical portion 24 has an extension 27 extending beyond the end of the canister body 18 to protect the valve stem 19. The extension 27 is of reduced diameter relative to the remainder of the cylindrical portion 24 of the collar 23.

The collars 21 and 23 are both formed with a weak portion constituted by two rupture lines 28 disposed on opposite sides of the collar 21 or 23 and arranged to be broken preferentially to the remainder of the collar 21 or 23 on application of a force to separate the closure element 16 from the canister 5. After the rupture lines 28 have been broken or at least deformed to enable removal of the canister 5, it is impossible to connect the collar 21 or 23 to a different canister.

The outer surface of the closure element 16 carries an indication of the type of medicament in the canister 5 to which the closure element 16 is connected. The indication may be printed information, an embossed or indented pattern or the colour of the closure element 16.

An inlet opening 29 is formed in the upper housing portion 3, in particular in its top wall 10 and front wall 8. The outer walls of the housing defined by the upper and lower portions 3 and 4 and the closure element 16 seal together to define a closed space which constitutes an air flow path extending from the mouthpiece 13 through the housing 2 to the inlet opening 29. Inhalation at the mouthpiece 13 draws air in through the inlet opening 29 through that air flow path around the canister 5 and actuation mechanism 6 encased in the housing 2. The actuation mechanism 6 (described in detail below) has a trigger disposed in the upper housing portion 4 which, in response to a flow through the air flow path, triggers the actuation mechanism 6 to actuate the canister 5.

If a canister without a closure element connected thereto is inserted into the housing 2, then the vent 15 will remain open as illustrated in Fig. 2A. Consequently, when a user inhales at the mouthpiece 13, the flow resistance through the vent 15 will be much lower than the flow resistance through the remainder of the air flow path above the vent 15 from the inlet opening 29. Accordingly, the vent 15 will vent

most of the flow through the mouthpiece, thereby reducing the flow in the remainder of the air flow path in the upper housing portion through. The positioning of the vent 15 in the air flow path inside the housing 2 between the mouthpiece 13 and the trigger reduces the air flow across the trigger. The vent 15 is positioned and dimensioned such that the flow at the trigger is reduced below the threshold needed to operate the trigger and therefore prevents operation of the actuation mechanism 6. To assist in assuring that the vent 15 sufficiently vents the flow, the vent 15 is provided with a larger opening area and hence a lower flow resistance than the inlet opening 29. The vent 15 is dimensioned so that the actuation mechanism is not operated on a flow through the mouthpiece 13 at a level above the maximum expected inhalation, for example at an inhalation of at least eight times a standard inhalation flow rate. The triggering mechanism for the actuation mechanism 6 is designed taking into account the flow generated by a standard inhalation selected by the designer.

The actuation mechanism 6 for actuating the canister 5 to deliver a dose of medicament is illustrated in Figs. 7 to 9. The elements illustrated in Figs. 7 to 9 are accommodated in the housing 2 but are illustrated separately for clarity. The canister 5 is held with its valve stem 19 in a nozzle block 20' connected to the mouthpiece 13, both fixed relative to the lower housing portion 4. A nozzle block 20' has a slightly different structural form from the nozzle block 20 illustrated in Figs 3 and 4 but performs the same function. The body 18 of the canister 5 is supported by a guide block 30 fixed to the upper housing portion 3 and having a curved inner surface engaging the cylindrical surface of the canister body 18 to allow axial movement of the canister body 18 within the housing 2. The actuation mechanism 6 operates to compress the canister body 18 relative to the valve stem 19 held in the nozzle block 20 to deliver a dose of medicament.

The structure of the actuation mechanism 6 is as follows.

The actuation mechanism 6 includes a pre-loading mechanism for loading a resilient loading element in the form of a coiled loading spring 31. The pre-loading mechanism includes the loading member constituted by a shaft 32 encircled by the coils of the loading spring 31. The shaft extends and is movable in a direction

parallel to the cylindrical axis 80 of the canister body 18. The loading member shaft 32 has an enlarged head 33.

As illustrated in Fig. 1, two buttons 34a and 34b, constituting contact members to be manually depressed, are mounted opposite one another in the side walls 7 of the upper housing portion 3 on either side of the axis 80 of the canister 5 held in the housing 2. The buttons 34 are manually depressible in a direction substantially perpendicular to the axis 80 of the cannister 5 which makes them easy to grip and move by a finger and thumb, as can be seen in Figure 1. The buttons 34 load the loading member 32 and loading spring 31 through the arrangement

illustrated in Fig. 10 comprising two torsion springs 35a and 35b fixed inside the upper housing portion. The torsion springs 35a and 35b engage the enlarged head 33 of the loading member 32 and respective ones of the buttons 34 to convert sideways force applied to the buttons 34 to a downwards force along the axis of the loading member shaft 32.

An alternative means for converting the sideways force applied to the buttons 34 is illustrated in Fig. 11. This consists of a double knee joint 36 fixed at its upper end 37 to the upper housing portion 3, fixed at its lower end 38 to the enlarged head 33 of the loading member 32 and fixed at its intermediate joints 39a and 39b to the respective buttons 34a and 34b.

The pre-loading mechanism further includes a lever 40 pivoted relative to the housing about a pivot 41. The lever 40 has a planar canister engagement portion 42 contacting the canister body 18 adjacent the pivot 41 with a pair of arms 43 and 44 extending therefrom. One arm 43 is engaged by the loading spring 31 so that the loading spring 31, when loaded, biases compression of the canister through the lever 40 coupled to the canister 5 by the canister engagement portion 42. As the loading spring 31 is further away from the pivot 41 than the cannister engagement portion 42, this provides leverage between the loaded actuation force and the force applied to the cannister 5. The arm 43 has a hole through which the loading member shaft 32 extends. The other arm 44 of the lever 43 has a similar hole through which extends a further shaft 78 for preventing lateral displacement of the lever 40.

The actuation mechanism further includes a triggering mechanism for

holding the lever 40 against compression of the canister under the biasing of the spring 31 and to release the lever 40 in response to inhalation at the mouthpiece. The triggering mechanism is constructed as follows.

The triggering mechanism comprises a first knee joint 45 having two links 5 46 and 47 connected pivotally to one another by a central pivot 50. The upper link 46 is pivotally connected both arms 43 and 44 of the lever 40 by a pivot 48. The lower link 47 is pivotally connected to the upper housing portion 3 by a pivot 49.

Accordingly, the first knee joint 45 has a locked position illustrated in Figs. 7 to 9 in which it holds the lever 40 against compression of the canister 5. In the 10 locked position of the first knee joint 45, the central pivot 50 is substantially aligned with the pivots 48 and 49 at the ends of the links 46 and 47. As the first knee joint 45 is connected to the lever at a position further away from the pivot 41 than the cannister engagement portion 42, this provides leverage between the locking force provided by the first knee joint and the force applied to the cannister 5. This leverage 15 enhances the locking and triggering action of the triggering mechanism.

The triggering mechanism further includes a second knee joint 51 comprising two links 52 and 53 connected by a central pivot 54. One link 52 of the 20 second knee joint 51 is pivotally connected to the upper housing portion 3 by a pivot 55 and extends laterally so that it constitutes a trigger vane which is moved by a flow of air thereover. The trigger vane 52 has a counterweight portion 79 (illustrated only in Fig. 7) fixed to the opposite side of pivot 55 from the laterally extending surface. The counterweight balances the trigger vane so that its centre of mass is positioned on the axis of the pivot 55.

The other link 53 of the second knee joint 51 extends from the trigger vane 25 52 between the arms 43, 44 of the lever 40 to the upper link 46 of the first knee joint 45 where it is pivotally connected by a pivot 56.

Accordingly, the second knee joint 51 has a locked position illustrated in Figs. 7 to 9. In the locked position of the second knee joint, the central pivot 54 is substantially aligned with the pivots 55 and 56 and the ends of the links 52 and 53.

30 The actuation mechanism 6 further includes a reset mechanism which is constructed as follows.

The reset mechanism employs a locking element constituted by a third knee joint 57 comprising an upper link 58 and a lower link 59 pivotally connected together by a central pivot 60. The upper link 58 is pivotally connected to the upper housing portion 3 by the pivot 49 in common with the first knee joint 45. The lower link 59 is pivotally connected to the loading member shaft 32 by a pivot 61. The third knee joint 57 has a locked position illustrated in Figs 7 to 9 in which it holds the loading member shaft 32 in its loaded position as illustrated in Fig. 7. In the locked position of the third knee joint 57, the central pivot 60 is aligned with the pivots 48 and 61 at the end of the links 58 and 59. The third knee joint 57 is also biased into its locked position by a biasing spring 67 connected to the upper housing portion 3. Hence the third knee joint constitutes a locking element which holds the canister in a compressed state through spring 31 and lever 40 after the full movement of the lever 40 to compress the canister 5.

The reset mechanism further includes a release member 62 mounted on the loading member shaft 32 by having an aperture through which the shaft 32 extends. The release member 62 is movable relative to the shaft 32 between limits defined by a pin 63 protruding from the shaft 32 engaging in a track 64 formed in the release member 62. A timer spring 65, the coils of which encircle the shaft 32, is connected between the arm 43 of the lever 40 and the release member 62. The timer spring 65 is in a relaxed state in Fig. 7 and is provided for biasing the release member 62 when loaded by movement of the lever 40 to compress the canister 5.

A protrusion 66 extends from the release member 62 (as best seen in the partial view of Fig. 12) to engage with the lower link 59 of the third knee joint 57 when the release member 62 is moved down the shaft 32. Such engagement of the protrusion 66 with the third knee joint 57 moves the knee joint 57 against the biasing spring 67 to break the third knee joint 57 thereby releasing locking effect of the third knee joint 57.

The shaft 32 is biased upwardly by a reset spring 68 acting between the shaft 32 and upper housing portion 3 to move the shaft 32 upwardly upon breaking of the third knee joint 57.

The downwards movement of the release member 62 is damped by a

damping element 69 consisting of a stator 70 fixed to the upper housing portion 3 and a rotor 71 rotatable through viscous fluid provided between the rotor 71 and stator 70. The rotor 71 is driven by a toothed rack 72 connected to the release member 62.

5 Operation of the actuation mechanism 6 will now be described with reference to Figs. 13 to 16 which illustrate the various parts of the actuation mechanism 6 in schematic form for ease of understanding.

Figure 13 illustrates the neutral state in which the loading member shaft 32 is in its uppermost position, so that the loading spring 31 is relaxed. In this state, the
10 first and second knee joints 45 and 51 are both in their locked positions. The timer spring 65 and the reset spring 68 are relaxed.

Upon depression of the buttons 34, the loading member shaft 32 is moved downwardly to a second position illustrated in Fig. 14 loading the loading spring 31 which therefore biases the lever 40 towards compression of the canister 5.
15 However, the first knee joint 45 is in its locked position where it holds the lever 40 against compression of the canister 5. The first knee joint 45 is held in its own locked position by the second knee joint 51 being in its locked position.

Movement of the loading member shaft 32 downwards also loads the reset spring 68 and brings the third knee joint 57 into its locked position where it is held
20 by the spring 67. In this loaded state illustrated in Fig. 14, the inhaler 1 is loaded ready for delivery of a dose of medicament.

Inhalation by the user at the mouthpiece 13 generates an air flow through the air flow path defined inside the housing 2 from the inward opening 29 to the mouthpiece 13. This air flow acts on the trigger vane 55 of the second knee joint 51
25 causing it to move upwardly due to pressure drop created by the flow inside the housing 2 to the position illustrated in Fig. 15 where the second knee joint is broken. This breaks the first knee joint 45 into its broken position illustrated in Fig. 15 which releases the lever 40 and allows it to compress the canister 5 under the biasing of the loading spring 31.

30 During compression of the canisters, the shaft 32 remains locked in position by the third knee joint 57. This causes the canister to be held in its compressed state

by the shaft 32 acting through the spring 31 and lever 40, the spring force of the spring 31 far exceeding the internal reset biasing of the canister 5.

However, movement of the lever 40 loads the timer spring 65 which accordingly biases the release member 62 downwards. Movement of the release member 62 is delayed by the damping action of the damping element 69. The protrusion 66 of the release element 62 engages the third knee joint 57 after a predetermined period of time after actuation of the canister 5. This time is determined by the strength of the timer spring 65 and the damping properties of the damping element 69 and is at least 100 ms or 200 ms and up to 1000 ms or 5000 ms to allow the full dose of medicament to be delivered from the cannister 5. Such engagement breaks the third knee joint 57 into its broken position as illustrated in Fig. 16. Subsequently the reset spring 68 moves the loading member shaft 32 upwardly to the neutral position illustrated in Fig. 13. At the same time the shaft 32 lifts the release member 62, itself still damped by the damping element 69 so that the reset movement is damped.

Release of the shaft 32 causes the spring 31 to raise the lever 40 which has two effects. Firstly it allows the canister to reset itself. Secondly, it causes the first and second knee joints 45 and 51 to straighten, returning them to their locked position in the neutral position of the actuator mechanism illustrated in Fig. 13. The loading spring 31 and the timer spring 65 are pre-loaded and do not work against the reset movement, so that the reset spring 68 has only to overcome friction and the weight of the component.

The buttons 34a and 34b protrude from the inhaler when the actuation is in its relaxed state as shown in Fig. 1 and are depressed to a position flush with the side walls 8 of the upper housing portion 3. Accordingly, the distance between the extremities of the buttons before depression is less than the maximum length of the inhaler 1 in the direction parallel to the axis 80 of the canister 5 and less than the overall length of the canister 5 including the body 18 and the valve stem 19. Also, the total distance over which the two buttons 34 are moved relative to one another is greater than the distance by which the body 18 and the valve stem 19 of the canister 5 are relatively compressed. This is achieved by the leverage obtained by the loading

spring 31 engaging lever 40 at a point further away from the pivot 41 than the canister engagement portion 42.

The actual flow recommended in order to correctly deliver a drug will depend on the manner operation of the drug, the position where it should be deposited in the mouth, lungs of the user and the manner of dispensing the drug. Some drugs are inhaled as a fine mist and transported all the way to the lungs whereas others are inhaled like a jet of liquid deposited in the mouth of the person. These different types of drugs require different types of inhalation and therefore different inhalation flows and different actions by the user.

It is possible to adapt each of a number of different inhalers for use with a number of different types of drug by giving each inhaler a vent with a different shape and giving different closure elements shapes which conform with a single type of inhaler. For example, a possible different shape is illustrated by the dotted line in Fig. 1. Thus canister with differently shaped closure elements are for use exclusively with the inhaler having a conforming vent. The different shapes may prevent a closure element from being fitted in an inhaler of the inhaler having a conforming vent. Alternatively, the closure element may fail to close the vent of an inhaler having a differently shaped vent such that the remaining opening vents the flow sufficiently to prevent operation of the triggering mechanism.